Implementation of a Rapid Testing Program: New Jersey

Sindy M. Paul, M.D., M.P.H. February 14, 2002

Epidemiology of HIV Disease in New Jersey: 12/31/00

- 43,009 Cumulative AIDS Cases 5th in US
- Highest proportion of women 28%
- Cumulative pediatric AIDS 3rd US
- 739/788 (94%) pediatric AIDS perinatal
- 397/420 (94%) pediatric HIV perinatal

Potential Initial Barriers

- Conduct a needs assessment (Show me the data!)
- Collaboration with surveillance staff
- Special studies
- Evaluate each step of the cascade to identify major gaps in reducing vertical transmission
- Be realistic do what is possible, not impossible

Needs Assessment: Gaps in Reducing the Risk

- Access to prenatal care: none known for 25% of HIV infected pregnant women
- 1999: 23% no known prenatal care 6% inadequate prenatal care (1-2 visits)
- >90% providers offer testing, >90% accept
- Serostatus knowledge: 91% HIV infected pregnant women know their serostatus prior to delivery (4% tested at delivery)

Needs Assessment: Gaps in Reducing the Risk - Cont'd

- ART use: increased from 8.3% in 1993 to 70% known in 1999
- Decrease in perinatal transmission from 21% in 1993 to 5.0% in 1999
- Room for improvement recent studies show vertical transmission can be as low as 1-2%
- What are the missed opportunities?

Missed Opportunities: Children Who Became Infected

- 7 children infected 1999, 1 infected 2000 (preliminary data reports through 12/31/00)
- 5 of the 8 (63%) no known or inadequate prenatal care
- 7/8 (88%) HIV status unknown to the delivery team

Missed Opportunities: Children Who Became Infected Continued

- 1 of the 8 (13%) had prenatal care starting in 3rd trimester with antiretroviral agents in pregnancy, labor/delivery, and neonatal period and a vaginal delivery
- Major gap: women presenting in labor with unknown HIV serostatus to the provider
- Contributing factor: lack of or inadequate prenatal care

Prevention of Perinatal HIV Transmission: ? Serostatus

- Rapid Test for Unknown Serostatus
- Short Course Therapy Options:
 - 1 dose NVP labor onset & 1 dose NVP for the newborn at age 48 hours
 - ZDV+3TC in labor &1 week ZDV+3TC for the newborn
 - -Intrapartum ZDV+6 weeks ZDV newborn
 - -2 dose NVP regimen + 6 weeks ZDV

Hospital Survey: Management Labor Unknown Serostatus

- Questionnaire survey of 12 hospitals Essex, Hudson, Union counties
- IRB approval
- 12 licensed acute care general hospitals
- 9/12 (75%) responded
- 6/9 (67%) provide obstetrical care
- 1 (10%) rapid test capability

Hospital Survey: Management Labor Unknown Serostatus

- 1/6 (17%) always offers CTS in labor
- 2/6 (33%) almost always offer CTS in labor
- 2/6 (33%) rarely or never offer CTS in labor
- 0 policy for rapid test/short course therapy
- 5/6 (83%) use standard EIA + Western Blot
- 1/6 (17%) use HIV DNA PCR
- Problem: obtaining results in time to treat infant with ZDV

Gap(s) to Be Addressed

- Lack of or inadequate prenatal care
- Women who present in labor with the delivery team unaware of her HIV status
- Lack of access to rapid or expedited diagnostic HIV testing
- Keep it simple all these gaps can be addressed through a standard of care

Developing A Statewide Standard of Care for Unknown Serostatus

- Identify & involve providers & other stakeholders
- Education
- Development of a statewide std of care
- Identification & approach to barriers
- Dissemination of information
- Implementation of the policy
- Evaluation

Stakeholder Identification

- Collaboration within NJDHSS
- Obstetricians & pediatricians
- Nurses, ICPs, social workers, case managers
- MCH consortia & Ryan White Title IV
- Medicaid
- Prevention
- AETC and AMNJ

Stakeholder Involvement: Initial Groundwork

- Individualized meetings and informal discussions with major stakeholders
 - Obstetrical Society
 - Pediatricians & Obs at hospitals
 - Ryan White Title IV sites
 - MCH consortia
 - Medicaid
 - NJDHSS
 - AMNJ

Stakeholder Involvement: Getting Everyone Together

- Initial meeting at NJDHSS
- Presentation of needs assessment
- Identification of common concerns & goals
- Discussion of potential strategies
 - Statewide policy
- Discussion of potential barriers
 - Cost
 - Test availability and capability

Barriers to Writing the Standard of Care: Why it Took 1 Year

- 70 stakeholders with > 70 opinions
- Holding many meetings
- Conflicting comments (as basic as what to call the standard of care)
- Consensus Building
- Education
- Departmental approval

Intent of the Standard of Care

• To decrease the risk of vertical transmission in every HIV exposed baby born in a New Jersey hospital to the best practice standards

Intent of the Standard of Care

- Provide HIV counseling and voluntary rapid or expedited testing of mothers or newborns if unknown HIV status or mother reports HIV infection with no documentation on the medical record
- Offer maternal &/or newborn ART if HIV
 +, mother reports being HIV +, or mother
 previously documented to be HIV +

Standard of Care: Women in Labor with ? HIV Status

- Provide counseling (pre- and posttest)
- Voluntary rapid or expedited HIV test
- If HIV positive provide preliminary lab results (CDC & ASTPHLD)
- If HIV positive offer short course therapy
- DO NOT DELAY RX pending confirmatory lab results
- Refer mother & child for follow-up care

Potential Barriers: Counseling

- How to present HIV counseling and offer testing during labor
- Development of model counseling session
 - Review of Lit & Discussion with CDC
 - Meetings teaching & non-teaching hospital staff
 - Focus group postpartum women
- Statewide TOT with MCH consortia

Potential Barriers To Implementation: Lab Concerns

- Cost: NJ law already required mandatory counseling and voluntary testing of pregnant women so substituting 1 test for another
- Test availability: 6 rapid tests in FDA; SUDS discontinued then available
- PPV problem with SUDS
- Lab misperception: preliminary + results

Potential Barriers - Continued

- Volume of testing required:
 - unknown serostatus not all 120,000
 - 1 hospital reported doing 30/year
 - Estimated 1,100-1,200 women (1% based on electronic birth certificate data) women with no prenatal care annually statewide
- Considered for women who test negative early in pregnancy

Dissemination of the Standard of Care

- Development & dissemination of a template counseling session for pregnant women
- Hospital mailing with a Laboratory Alert
- Health Bulletin for physicians and hospitals
- Continuing education programs
- Web-based CME www.acadmed.org
- Hospital TA
- Articles for Publication: medical & lab

Summary of Continuing Education 2001

- Total:197 physicians, 197 nurses, 216 other
- Roving Symposia (11 with 213 attendees)
- 117 physicians, 43 nurses, 53 other
- Statewide Conferences (3 with 385 attend)
- 74 physicians, 153 nurses, 158 other
- Web-based CME (19 "hits" 12 CME)
- 6 physicians, 1 nurse, 5 other

Dissemination - Continued

- Collaboration with NJDHSS hospital licensure staff
- Collaboration with the Board of Medical Examiners
 - License physicians and nurse midwives
- Collaboration with OB Society & ACOG
 - Annual OBGYN Conference & mailings

Evaluation of Implementation & Effectiveness

- Repeat questionnaire survey
- Surveillance data for women presenting with unknown serostatus
 - # positive rapid tests
 - # short course therapy
 - # children who serorevert
 - # children infected
- Retrospective medical record review

Conclusion

- A statewide standard of care can be developed, implemented, & evaluated
- Anticipate barriers
- React to new barriers as they arise
- Patience
- Consensus building
- Continually work with stakeholders